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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590	02/05/2004		EXAMINER	Rao, Manjunath N
VICTORIA L. BOYD Genencor International, Inc. 925 Page Mill Road Palo Alto, CA 94034-1013			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/027,000	DUNN-COLEMAN ET AL.
	Examiner Manjunath N. Rao, Ph.D.	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-36 is/are pending in the application.
- 4a) Of the above claim(s) 18,21,25 and 27-36 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-17,19,20,22-24 and 26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) Interview Summary (PTO-413) Paper No(s). _____ .
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

DETAILED ACTION

Claims 2-36 are now currently pending in this application. Claims 2-17, 19-20, 22-24 and 26 are now under consideration. Claims 18, 21, 25, 27-36 remain withdrawn from consideration as being drawn to non-elected invention.

Applicants' amendments and arguments filed on 11-20-03, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (for e.g. See p. 18). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended claim 2 and claims 3-17, 19-20 which depend therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the phrase “ β -glucosidase IV endoglucanase activity”. It is not clear to the Examiner as to which specific activity i.e., β -glucosidase or endoglucanase that applicant is referring to. As per the

specification these two activities are subtly different even though they are both classified as cellulase. Correction is required.

Claim 2 and claims 3-17, 19-20 that depend therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is drawn to a polynucleotide selected from a group of different polynucleotides. However, in parts (a) and (b), the polynucleotide is referred to as encoding a polypeptide having a certain % sequence identity to the amino acid sequence presented in "Figure 2 (SEQ ID NO:2)". This recitation is confusing. This is because it is not clear whether said polypeptide specifically has the amino acid sequence with SEQ ID NO:2 or to that represented in figure 2. The recitation indicated above is confusing because it gives an impression to those skilled in the art that the amino acid sequence represented in figure 2 is the same as the amino acid sequence SEQ ID NO:2. Furthermore, a perusal of figure 2 and its description indicates the sequence as having SEQ ID NO:2 without any reference to signal sequence or mature enzyme sequence, which adds to the confusion.

In their response to the previous objection by the Examiner, applicants have traversed the objection arguing that figure 2 depicts the enzyme with its secretion signal while SEQ ID NO:2 recites the mature sequence (without secretion signal) and thus two different molecules are being referred to in different parts. However, a perusal of figure 2 and its description does not lead one to the above conclusion. Therefore claim 2 and claims depending therefrom continues to be indefinite.

Claims 6, 7, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6, 7 recite the phrase "derived from". The metes and bounds of this phrase in claims is not clear to the Examiner. Literally, while the term "derived" means "to isolate from or obtain from a source", the above term could also mean "to arrive at by reasoning i.e., to deduce or infer" or also mean "to produce or obtain from another substance" (see enclosed copy from Dictionary). Therefore, it is not clear to the Examiner either from the specification or from the claims as to what applicants mean by the above phrase. It is not clear to the Examiner whether the "derived from a fungal source or derived from *Trichoderma*" encompasses only *Trichoderma* as in "isolated from a fungal source or isolated from *Trichoderma*" or whether it encompasses recombinants, variants and mutants obtained from any source and labeled as "derived from a fungal source or derived from *Trichoderma*". As applicants have not provided a definition for the above phrase, Examiner has interpreted the claims broadly to mean, that a "derived from" encompasses all or any source. Examiner has given the same interpretation while considering the claims for all other rejections.

In response to the previous Office action, applicant has traversed the above rejection and indicated that applicant has not used the above phrase in a fashion that is antithetical to its common meaning and has amended the claims. However, claims 6-7 continue to recite the above phrase and thus remains unclear due to the reasons explained above. Examiner suggests the phrase "isolated from".

Claims 8-9, 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 8 and 9 recite the phrases "including a polynucleotide" and "including the expression construct". The meaning of the above phrase in the context of the above claim is not clear to the Examiner. It appears that applicant intended to recite "comprising a polynucleotide", and "comprising the expression construct" respectively. If this is so amending the claim accordingly would overcome this rejection.

In response to the previous Office action, applicant has indicated that the claim has been amended to recite "comprising" rendering the above rejection moot. However, such an amendment has not been made. Hence the above rejection is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 and claims 3-17, 19-20 that depend therefrom are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 2 now appears to directed to endoglucanase as well as β -glucosidase. A perusal of the specification indicates that the invention is a β -glucosidase and has no support for an endoglucanase. Therefore claim

2 and claims depending therefrom are rejected for introducing "new matter" that has not been described in the specification.

Claims 1-17, 19-20, 22, 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide isolated from *T.reesei*, with SEQ ID NO:1, 3 encoding a polypeptide with SEQ ID NO:2 having β-glucosidase activity and a method of making said β-glucosidase by transforming a host cell with an expression vector comprising the polynucleotide with SEQ ID NO:3 followed by cultivating the host cells and recovering the expressed beta-glucosidase, a recombinant host cell in which the polynucleotide with SEQ ID NO:3 has been inactivated such that it does not express a functional beta-glucosidase, does not reasonably provide enablement for a polynucleotide isolated from any all sources, or a polynucleotide that has 85%, 90%, or 95% identity to the polynucleotide encoding the polypeptide with SEQ ID NO:2 or any such polynucleotides that hybridizes under high stringency conditions to SEQ ID NO:3 or polynucleotides that hybridize under intermediate to high stringency conditions to the polynucleotide encoding polypeptide with SEQ ID NO:2, and having β -glucosidase activity and a method of making said β-glucosidase by transforming a host cell with an expression vector comprising the said polynucleotide followed by cultivating the host cells and recovering the expressed beta-glucosidase or a recombinant host cell in which any polynucleotide encoding any β-glucosidase has been inactivated such that it does not express a functional β-glucosidase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

With respect to claims directed to variant polynucleotides encoding polypeptides that have 85%, 90%, or 95% sequence identity to SEQ ID NO:2, applicants have not taught those skilled in the art as to how to make and select the claimed polynucleotides, which leads to undue experimentation. Since the amino acid sequence of a protein encoded by a given polynucleotide, determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence to obtain the desired activity, requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant to modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only a single β-glucosidase, obtained from *T.reesei* and having an amino acid sequence SEQ ID NO:2 . Putting it in simpler terms, the specification is silent regarding the specific amino acids or specific regions in the amino acid sequence of SEQ ID NO:2 that can be modified (by insertion, deletion or substitution) without affecting the β-glucosidase activity which could be used to construct variant polynucleotides. Therefore, it would require undue experimentation by a skilled artisan to identify such regions that can be changed and make and

use all the claimed variant polynucleotides. The specification is limited to teaching the use of just SEQ ID NO:3 as polynucleotide encoding the polypeptide with SEQ ID NO:2. In view of the great breadth of the claim, amount of experimentation required to make the claimed polynucleotides, the lack of a universal method of isolating polynucleotides encoding an β -glucosidase from any fungi and lack of guidance regarding where to make the changes in the polypeptide/nucleotide sequences, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892) to make a polynucleotide sequence, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to make and use the full scope of the polynucleotides encompassed by this claim.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass polynucleotides encoding β -glucosidase from any or all fungi, encompassing polynucleotides with any or all modifications and fragments encoding a polypeptide with 85%, 90%, or 95%

identity to the SEQ ID NO:2 or polynucleotides that hybridize under intermediate to high stringency conditions to a probe (of any length or function) designed to hybridize to the polynucleotide with SEQ ID NO:3, because the specification does not establish: (A) a single universal method to isolate polynucleotides encoding β -glucosidase from any fungi; (B) a single universal method to inactivate polynucleotides encoding β -glucosidase from any fungi in any host cell; (C) regions in the polynucleotide structure which may be modified without effecting its activity of encoding a functional β -glucosidase; (D) the general tolerance of said polynucleotide sequence to modification and extent of such tolerance; (E) a rational and predictable scheme for modifying any nucleotide in any fungal polynucleotide with an expectation of obtaining the desired biological function; and (F) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

On similar lines, while applicants have provided SEQ ID NO:3 and host cells comprising such polynucleotides, and those skilled in the art would be enabled to inhibit such host cells from expressing β -glucosidase encoded by SEQ ID NO:3 by going in and making changes to SEQ ID NO:3, they have not provided methods to do the same with host cells expressing any fungal β -glucosidase because applicants have not provided methods to isolate such polynucleotides in the first place. Therefore without such polynucleotides, those skilled in the art would be unable to make host cells containing such polynucleotides in the first place. Furthermore, applicants have also not taught a universal method that can be used to inactivate any fungal polynucleotide encoding β -glucosidase in any host cell. Therefore claims drawn to host cells in which polynucleotides encoding β -glucosidase are inactivated remain non-enabled.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides from any fungi or polynucleotides with an enormous number of modifications of to the polynucleotide encoding the amino acid with SEQ ID NO:2 (SEQ ID NO:3). The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office action, applicants have traversed the above rejection. Applicant argues that because the court overturned the enablement rejection in one specific case (*In re Dinh-Hguyen*, 181 USPQ 46(CCPA 1974)), the instant enablement rejection must be withdrawn as the situation in the instant case is similar to the case involved in the above court ruling. Examiner is not aware of the claims involved, claim language and the prosecution history of the above case and is therefore unable to concur with the applicant. Applicant also alleges that the Office action provides no extrinsic evidence regarding non-enablement, instead relies up on the opinion of the Examiner that the breadth is unsupportable because there aren't enough examples. Applicant also alleges that the Office action is entirely devoid of technical reasoning and/or evidence which supports the position therein etc. Examiner respectfully disagrees with such a misplaced and highly tangential argument by the applicant. On the contrary Examiner submits that the previous and the present rejection are not based on Examiner opinions and the analysis has been done based on Wands factors and scientific reasons. Indeed applicant's claims

are directed to extremely large number of polynucleotides. Applicant is claiming any or all polynucleotides encoding β -glucosidase literally from any or all fungi that encode polypeptides that are 85%, 90%, and 95% identical SEQ ID NO:2. A simple mathematical calculation would indicate those skilled in the art that this amounts to an "extremely large number of polynucleotides" not supported by the applicant's specification. Examiner would like to reiterate that he has analyzed the claims based on the "Wands factors" and scientific facts.

With respect to variant polynucleotides, applicant's arguments are not persuasive because while methods to produce variants of a known sequence, such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing variants as claimed by applicants requires that one of ordinary skill in the art be provided with guidance for making specific changes and for the selection of which of the large number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) a single universal method to isolate polynucleotides encoding β -glucosidase from any fungi; (B) a single universal method to inactivate polynucleotides encoding β -glucosidase from any source in any host cell; (C) regions in the polynucleotide structure which may be modified without effecting its activity of encoding a functional β -glucosidase; (D) the general tolerance of said polynucleotide sequence to

modification and extent of such tolerance; (E) a rational and predictable scheme for modifying any nucleotide in any fungal polynucleotide with an expectation of obtaining the desired biological function; and (F) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Therefore the above rejection is maintained.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This claim is directed to a host cell comprising a genus of DNA molecules whose capability to encode a functional beta-glucosidase is inactivated.

The specification does not contain any disclosure of the structure of all DNA sequences that are encompassed by the claims. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of having many different structures. Therefore, many structurally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office action, applicant has traversed the above rejection arguing that Examiner has not presented adequate or sufficient reasoning for the rejection. Without acquiescing to such arguments, Examiner has withdrawn the above rejection because of the specific claim amendments except for claim 22 which continues to lack structure of the polynucleotide.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takashima et al.(J. Biochem., Vol. 125:728-736, 1999) and the common knowledge in the art. This rejection is based upon the public availability of a printed publications. Claim 22 of the instant application is drawn to a recombinant host cell comprising a deletion or insertion or other alteration in the bgl4 gene which inactivates the gene and prevents β -glucosidase polypeptide production.

Takashima et al. teach a host cell comprising a polynucleotide, encoding a beta-glucosidase, bgl4, isolated from a *Trichoderma* sp., a method of producing said beta-glucosidase using the transformed host cells, a method of expressing a heterologous polypeptide having beta-glucosidase activity in an *Aspergillus* species (see page 730, column 2) by transforming a *Aspergillus* host cell with an expression vector comprising a polynucleotide encoding a signal sequence linked to a polynucleotide encoding a heterologous beta-glucosidase encoding a chimeric polypeptide followed by cultivating said host cell such that the chimeric

polypeptide is produced. However, the reference does not teach a recombinant host cell comprising a deletion or insertion or other alteration in the bgl4 gene which inactivates and prevents β -glucosidase polypeptide production.

With the above reference in hand and the common knowledge in the art that introducing a stop codon in the middle of the sense sequence or that deletion of a major portion of the coding sequence from a cDNA sequence inactivates the encoded protein, it would have been obvious to those skilled in the art to take the cDNA encoding bgl4, provided by Takashima et al. and alter it either by a simple deletion of a major portion of the cDNA using a restriction enzyme or by introducing a stop codon after 20 or 30 nucleotides and religating the vector and transforming a host cell to obtain a transformed host cell deficient in encoding said β -glucosidase. One of ordinary skill in the art would have been motivated to do so in order to use such cells as control cells in experiments involving host cells encoding said β -glucosidase. One of ordinary skill in the art would have a reasonable expectation of success since Takashima et al. provide the required cDNA and the art teaches methods to do any alteration of the said cDNA. Therefore, the above invention would have been *prima facie* obvious to those skilled in the art.

Conclusion

Claims 23-24 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



MANJUNATH RAO
PATENT EXAMINER
Manjunath N. Rao
February 2, 2004